

REMARKS

The examiner has rejected claim 25 under 35 U.S.C. §112, second paragraph, as indefinite. The amendment made to the claim is believed to address and overcome the examiner's indefiniteness concerns.

The examiner has rejected the independent claims (1, 11, 16, 25) under 35 U.S.C. §103 as unpatentable over Gliner (US 6178357) in view of Kay (US 5713842). The examiner is urged to reconsider and withdraw the rejection, particularly in light of the amendments made to the claims. (The amendments have been made without prejudice to the original claims being pursued in a continuation application.)

The invention addresses a problem with external defibrillation electrodes, which are quite large (e.g., 4- 5 inches in diameter), relatively thick, and which have a very sticky adhesive to assure good adhesion to the patient. The rescuer must quickly attach the electrodes to the patient in a stressful, emergency situation, and the electrodes must be attached accurately at specific anatomic locations. Application of conventional defibrillation electrodes involves removing a release sheet from an electrode, and then placing the electrode on the patient's chest. As the rescuer begins to place the electrode on the chest, the adhesive will often stick prematurely to the patient's skin or chest hair and limit the rescuer's ability to relocate the electrode to the desired anatomic location. If a portion of the adhesive attaches itself to the patient at an unintended place, significant effort is required to detach the adhesive from the patient before finally placing the electrode at the desired location. This detachment/reattachment process can consume too much time, and result in a dangerous delay of treatment. The invention solves this problem of adhesion to an unintended place by allowing the rescuer to place the electrodes in the desired location, and to fine tune the chosen location, all before removing the release sheet.

Gliner shows a conventional defibrillation electrode in which the release sheet must be removed before the electrode can be positioned on the patient. This arrangement has been in use for decades without improvement.

Kay teaches a release backing for a thin wound dressing. To assure that the thin dressing is applied smoothly to form an occlusive seal without wrinkling, a U-shaped release backing is configured to be removed after the wound dressing is in position over the wound. The wound

dressings in question are very thin ("less than 2 mils", 1:33) and thus very susceptible to wrinkling, and because the purpose of the wound dressing is to seal the wound, any slight wrinkling must be avoided, as wrinkles prevent the achievement of the occlusive seal necessary to maintaining sterility in the wound. It is in this context, that Kay teaches the use of the U-shaped release backing -- as a means of solving a problem of wrinkling in the application of thin-film wound dressings to the skin.

It would not have been obvious to modify Gliner to substitute the U-shaped release backing of Kay for the conventional release backing taught in Gliner. No problem is taught in Gliner or in Kay that would provide any motivation for the combination. The problem of wrinkling that Kay addresses is not present in Gliner or in any defibrillation electrode. The electrodes are much thicker, and thus wrinkling does not tend to occur. And even if some does occur, it is not the critical problem that it is with a wound dressing, as it is not necessary to provide an occlusive (and thus sterile) seal between a defibrillation electrode and the skin.

Furthermore, one has to keep in mind the long history of conventional release liners in external defibrillation electrodes. Gliner was following a long accepted approach to release liners. It is simply not reasonable to conclude that one skilled in the art would have departed from that long-accepted release liner configuration to achieve an objective (wrinkle avoidance) that was not relevant to such electrodes. That person of ordinary skill would simply not have been motivated to look for the wrinkle-avoidance solution taught in Kay.

Finally, there is serious question as to whether Kay is even analogous art, as wound dressings are hardly the area of medical technology that designers of defibrillation electrodes would examine for solutions to problems.

Accordingly, the independent claims are in condition for allowance.

The remaining claims are all properly dependent on one or more of the independent claims, and thus allowable therewith. Each of the dependent claims adds one or more further limitations that enhance patentability, but those limitations are not presently relied upon. For that reason, and not because applicants agree with the examiner, no rebuttal is offered to the examiner's reasons for rejecting the dependent claims.

Allowance of the application is requested.

Applicant : Michael R. Dupelle et al.
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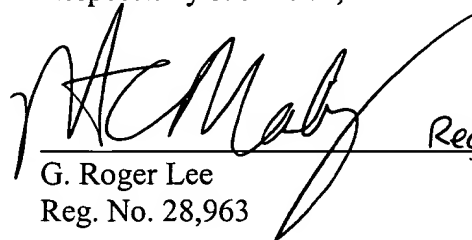
Attorney's Docket No.: 04644-101001

Attached is a marked-up version of the changes being made by the current amendment.

Enclosed is a check for \$110 in payment of the fee for the requested one-month extension of time. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 2/24/03


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Version with markings to show changes made

In the claims:

Claim 1, 11, 16, and 25 have been amended as follows:

1. (Amended) A generally planar skin-applied electrode pad for external defibrillation comprising:
an electrode sized for external defibrillation;
an adhesive configured to adhere the electrode to a patient's skin; and
a release sheet, a first portion of the release sheet covering the adhesive, and a second portion of the release sheet extending from the first portion and being folded so that the release sheet can be peeled away from the adhesive by pulling the second portion in a direction substantially parallel to the plane of the electrode pad while the electrode pad is held in a desired location on the patient.

11. (Amended) A skin-applied electrode pad for external defibrillation comprising:
an electrode sized and configured for external defibrillation;
an adhesive configured to adhere the electrode to a patient's skin; and
a release sheet covering the adhesive, the release sheet being configured to be removed while the electrode pad is held in a desired position on or against the patient's skin with a portion of the release sheet in contact with the patient's skin.

16. (Amended) A defibrillator comprising:
a defibrillator control box;
a pair of electrode pads for external defibrillation; and
leads connecting the electrode pads to the defibrillator control box;
wherein each electrode pad comprises:
(i) an electrode sized and configured for external defibrillation;
(ii) an adhesive configured to adhere the electrode to a patient's skin; and

(iii) a release sheet, a first portion of the release sheet covering the adhesive, and a second portion of the release sheet extending from the first portion and being folded so that the release sheet can be peeled away from the adhesive by pulling the second portion in a direction substantially parallel to the plane of the electrode pad while the electrode pad is being held in a desired position on the patient.

25. (Amended) A method of applying an external defibrillation electrode to a patient, the external defibrillation electrode including an adhesive portion covered by a release sheet, comprising:

positioning the external defibrillation electrode on the patient's skin with the release sheet facing the skin and in contact with or closely adjacent the skin;

without lifting the external defibrillation electrode from the patient's skin, removing the release [paper] sheet to expose the adhesive portion; and

adhering the adhesive portion to the patient's skin.